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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,692

09/30/2005

Toshiki Nishizawa

NISHIZAWA3

5980

1444 7590 02/22/2007
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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

02/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/551,692

Applicant(s)

NISHIZAWA, TOSHIKI

Examiner

Karen Cochran Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 10, and 11, drawn to polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 530, subclass 350.
- II. Claim 8, drawn to polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 536, subclass 23.1.
- III. Claim 9, drawn to microorganism comprising the polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 435, subclass 252.3.
- IV. Claim 9, drawn to plant comprising the polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 800, subclass 200.
- V. Claim 9, drawn to an animal comprising the polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 800, subclass 2.
- VI. Claims 12-15 and 20, drawn to a method of producing an antibody by administering polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 514, subclass 2.
- VII. Claims 16 and 17, drawn to a method of producing an antibody by administering polynucleotide encoding polypeptide comprising at least 1 cell attachment

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motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 514, subclass 44.

- VIII. Claims 18 and 19, drawn to method of producing antibody by administering microorganism comprising the polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 435, subclass 252.3.
- IX. Claims 18 and 19, drawn to method of producing antibody by administering plant comprising the polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope, classified in class 800, subclass 200.
- X. Claims 18 and 19, drawn to method of producing antibody by administering an animal comprising the polynucleotide encoding polypeptide comprising at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope.

Upon election of any one of Inventions I-X, Applicants must elect a single sequence for search.

Independent Claim 1 recites peptides having at least 1 cell attachment motif or 1 or more cell adhesion molecules plus a T cell epitope linked to a B cell epitope. This claim reads on thousands of peptide sequences that are not related in structure or function, and therefore this claim is considered to comprise an improper Markush group. This claim is not a proper linking claim because it, in fact, comprises multitudes of unrelated sequences.

Applicants may choose any number of cell attachment motifs SEQ ID NO: 2-11 AND must choose a single B cell epitope from Claim 7. It will be understood that ALL motifs chosen and the epitope chosen will be found in a single polypeptide.

Applicants must choose a single sequence for examination. **This is not a species election, but an election of a single invention.**

If Applicants believe that their sequences are so overlapping as to be obvious variants of each other, Applicants may choose a single sequence for search, this sequence being a representative sequence of all sequences or a designated subset of the sequences, as

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Applicant may choose. If Applicant present a single sequence to represent all sequences claimed, it will be understood that if this sequence or any sequence is found, the remaining sequences will be considered to be obvious variants of the found sequence.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions III, IV, and V are different products. While these products comprise the DNA of Invention II, once placed in a microorganism, plant, or animal, the characteristics are patentably distinct.

The polypeptide of Invention I is not used to make the products of Inventions III, IV, or V and is therefore patentably distinct therefrom.

Inventions I and VI, or Inventions III and VII, or Inventions III and VIII, or Inventions IV and IX, or Inventions V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any of the combinations above.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

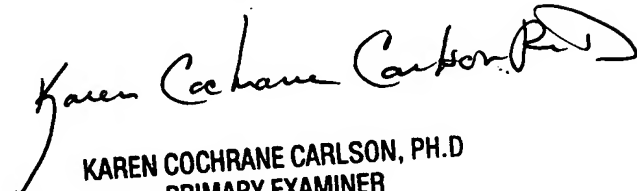
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER